

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re the application of:

Lasse LEINO et al.

Serial Number: 10/534,988

Group Art Unit: 1612

Filed: May 16, 2005

Examiner: Simmons, Chris E.

For: PHARMACEUTICAL COMPOSITION FOR INTRACELLULAR  
ACIDIFICATION WITH CIS-UROCANIC ACID

**PETITION FOR WITHDRAWAL OF FINALITY OF OFFICIAL ACTION**

Commissioner for Patents

**ATTN: Technology Center Director**

P.O. Box 1450

January 30, 2009

Alexandria, VA 22313-1450

Sir:

Applicants petition for withdrawal of the finality of the Fourth Official Action mailed December 1, 2008. The facts supporting this Petition follow:

1. This application previously claimed a method for treatment of a local inflammatory disease or disorder, comprising administering to a person or animal in need of said treatment a pharmaceutically acceptable agent or salt capable of acidifying cell cytoplasm,

wherein an effective amount of said agent is administered in non-dissociated form to said person or animal, and

wherein said agent is mixed with a carrier to adjust the pH of said composition to a pH range of 6.1 to 7.0.

2. On May 2, 2008, the Patent Office mailed a Third (Final) Official Action which contained two obviousness rejections and two provisional obvious-type double patenting rejections.

3. A Request for Continued Examination (RCE) with a submission and fee pursuant to 37 C.F.R. § 1.114 were filed September 2, 2008. The 37 C.F.R. § 1.114(a) submission was an Amendment After Final Rejection together with two supporting references.

3A. Claim 16, the sole independent claim, was amended to require said agent to be an acid having a dissociation constant in the range of 6.7 to 7.4. This new limitation was used to traverse both obviousness rejections. See page 9, paragraph No. 5 and page 11, lines 8-15 of the Amendment After Final Rejection.

3B. Two new references (Murahata et al. and Antoine et al.) were submitted to demonstrate those of ordinary skill in the dermatologic arts would not believe a relatively neutral pH of an applied agent will minimize skin irritation. This issue is important to whether the primary and secondary references cited in the first obviousness rejection are properly combined.

3C. The applicants also cited a theoretical estimate based on structural calculations available on the Internet

(<http://ibm1c2.chem.uga.edu/sparc/>.) to argue the acid dissociation constant (pKa) of a prior art compound (AG18) is 8.4, and thus outside of newly-amended claim 16.

4. The Fourth Official Action maintains each of the previous rejections in the Third (Final) Official Action. Importantly, a new reference (Baranda et al.) is cited to support the first obviousness rejection by allegedly disclosing a correlation between pH and skin irritation. Another new reference (a STN Registry database printout for compound AG18) is cited to show the pKa of compound AG18 is 7.24 +/- 0.18, and thus allegedly within the newly-inserted pKa range of claim 16.

5. The *only* basis cited for making the Fourth Official Action final is MPEP § 706.07(b). See page 5, lines 7-12 of the Fourth Official Action.

6. This Petition is timely, as it is being filed within two months of the December 1, 2008 mail date of the Fourth Official Action.

#### **ARGUMENT**

The finality of the Official Action should be withdrawn because (1) MPEP § 706.07(b) does not apply to this situation, and

(2) clear issues have not yet been developed between the Examiner and the applicants.

I. **MPEP § 706.07(b) Does Not Apply to This Application**

MPEP 706.07(b) permits an examiner to finally reject an application immediately after the filing of an RCE only in the situation where the claims were not amended, i.e., where all of the claims in the application after entry of the submission under 37 C.F.R. § 1.114(a) are drawn to the same invention claimed in the application prior to entry of the submission under 37 C.F.R. § 1.114.

The Amendment After Final Rejection submitted with the RCE amended claim 16, the only independent claim. Accordingly, all of the claims in the application after entry of the Amendment are drawn to a different invention than that claimed in the application prior to entry of the Amendment After Final Rejection. MPEP § 706.07(b) is simply not applicable.

II. **No Clear Issue Has Been Developed Between The Examiner and the Applicants**

MPEP § 706.07 requires a clear issue be developed between an examiner and the applicant prior to imposing a final rejection. In this case, there are at least two issues which have yet to be resolved:

1. Whether those of ordinary skill in the art believe there is a correlation between the pH of a skin agent and skin irritation; and

2. Whether compound AG18 has a dissociation constant in the range 6.7 to 7.4.

Both these issues are important to the patentability of the claims, and neither was resolved prior to imposition of the final rejection. Instead, both the applicant and the Patent Office have cited new documents to support their respective positions in their last submissions.

Imposition of a final rejection is premature. The applicants are entitled to a full and fair opportunity to review the newly-cited documents and, if appropriate, to amend the claims, file a Rule 132 declaration, or take other action to deal with these newly-cited documents.

**ACTION REQUESTED**

Applicants request the finality of the Official Action mailed December 1, 2008 be withdrawn.

U.S. Patent Appln. S.N. 10/534,988

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It is not believed any fee is required in connection with this Petition. Nevertheless, the Patent Office is authorized to charge any such required fee to Deposit Account No. 50-1258.

Respectfully submitted,

/James C. Lydon/

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